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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,614	07/19/2006	Everson Luiz de Almelda Artifon	P08915US00/BAS	6535

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EXAMINER	
WACHTEL, EMILY L	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,614	ARTIFON ET AL.	
	Examiner	Art Unit	
	EMILY WACHTEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 June 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *August 8, 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed August 8, 2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the reference by Demling et al. is not in English nor is there a concise statement of relevance. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: reference character A. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the guiding line, the external concentric tube attached to the manipulation component of the perforation tube is not clearly shown, and the external concentric tube comprising reinforcements and the reinforcements at the first and second extremities must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because in the instant case the abstract exceeds 150 words. Correction is required. See MPEP § 608.01(b).

6. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: in claim 9 the recitation that the external concentric tube having a first extremity attached to the manipulation component does not appear to be disclosed in the specification, in claim 15 reinforcements placed in the first and second opposite extremity do not appear to be disclosed in the specification, and the specific steps in claims 22-24 do not appear to be disclosed in the specification.

8. The disclosure is objected to because of the following informalities: on page 7 lines 7-13 when referring to Figures 2 and 3 it is believed the explanations have been reversed as Figure 2 shows the needle exposed and Figure 3 shows the non-exposure of the needle.

Appropriate correction is required.

Claim Objections

9. Claims 9-24 are objected to because of the following informalities: claims 10-22 are dependent off of claim 1, it is believed these claims are meant to depend off of claim 9 and they are treated as such. Claims 23-24 are dependent off of claim 14, these claims do not find antecedent basis for their subject matter in claim 14; it is believed they are meant to depend off of claim 22 and are treated as such. Claim 15 recites the limitation 'the reinforcements' there is insufficient antecedent basis for this limitation in the claim. Claim 24 recites the limitation 'the guiding line' there is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

10. Claim 13 is objected to because of the following informalities: it is unclear what is meant by the term 'composed material'.

11. Claims 9-24 objected to because of the following informalities: the term "artifon catheter" in the preamble has not been given a special definition in the specification. Therefore, the term is being given the same patentable weight as would be given to a preamble referring to a "catheter". Further, the term "perforating or perforation tube" is being given the same patentable weight as would the term "tube".

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 15 recites the limitation "the first and second opposite extremity" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is indefinite as to whether it is the first and second extremity of the external tube or the perforating tube. For purposes of examination it is being interpreted as the first and second extremity of the external tube.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 9-13, 19-21, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holsinger et al. (US 5,843,091) in view of Andrews et al. (US 6,482,178 B1).

With regard to claims 9, 19, and 21, Holsinger et al. teach an artifon catheter comprising: (a) a concentric perforating tube (Fig. 6A member 204) attached to a manipulation component on a first extremity (Fig. 6A assembly 200) and to a needle on a second opposite extremity (Fig. 6A needle 204); (c) an external concentric tube (Fig. 6A tube 208) having a first extremity attached to the manipulation component of the perforation tube and a second opposite extremity; internally bearing the concentric perforation tube, the needle and the radiopaque mark component, and having an external manipulating component adjacent to the manipulation component of the perforation tube (Fig. 1A member 12A - shown but not labeled in Fig. 6A); (d) a retraction blockage component externally attached to the external concentric tube portion (Device can incorporate external locking mechanism as described in Col. 12 lines 53-65 and would be attached to the external concentric tube via the end of assembly 200), and (e) an Y-

shaped connector linearly attached to the manipulating component of the perforating tube (Fig. 1A member 14 - shown but not labeled in Fig. 6). Holsinger et al. does not specifically teach a radiopaque mark component externally attached to the needle. However, Andrews et al. teach it is well known in the art to place a gold, biocompatible radiopaque element on the distal end of a device to make the element visible to the user (Fig. 1 component 19, Col. 2 lines 1-7). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a radiopaque mark component externally attached to the needle in the device of Holsinger et al. because Andrews et al. teach using radiopaque elements is well known and routine in the art for allow the user to visualize the device.

With regard to claim 10, needle 204 comprises a lumen (Col. 13 lines 5-9) and is capable of delivering a guiding line.

With regard to claim 11, assembly 200 can be attached via a luer lock as in member 314 of Figs. 8 and 9.

With regard to claim 12, Holsinger et al. teach a catheter substantially as claimed. Holsinger et al. does not disclose what the manipulation component is made out of or specifically that it is a thermoplastic polymer. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to make the manipulation component out of a thermoplastic polymer because Applicant has not disclosed that such a material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the manipulation component of Holsinger et al. made form a variety of materials because it provides the device with the needed dimensional stability.

With regard to claim 13, member 208 is necessarily made of a material that is composed and it facilitates the sliding of member 204 through it.

With regard to claim 20, the device is used with an endoscope (Col. 8 line 5).

With regard to claims 22-24, see Col. 8 lines 1-41. Specifically, regarding claim 23, the device can be locked in an extended position for use (Col. 12 lines 53-65).

17. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holsinger et al. (US 5,843,091) and Andrews et al. (US 6,482,178 B1) as applied to claim 9 above, and further in view of Forsberg (US 6,635,047 B2).

With regard to claims 14-15, Holsinger et al. teach a catheter substantially as claimed. Holsinger et al. does not disclose the external tube to have reinforcements. However, Forsberg teaches a catheter tube with metal and polymer reinforcement layer along its length which would necessarily include the extremities at either end (Col. 2 lines 58-67) and further that it is known in the art to reinforce catheters (Col. 1 lines 12-13). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to reinforce the catheter tube in the device of Holsinger et al. because Forsberg et al. teach it is beneficial for reinforcing a catheter and that such is well known in the art.

18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holsinger et al. (US 5,843,091) and Andrews et al. (US 6,482,178 B1)as applied to claim 9 above, and further in view of de Toledo et al. (US 5,785,689).

With regard to claim 16, Holsinger et al. teach a catheter substantially as claimed. Holsinger et al. does not disclose the external tube to be made of PTFE. However, de Toledo et al. teach using PTFE tubing for catheters because it can be easily advanced around bends and is impervious to and compatible with therapeutic and bodily fluids (Col. 4 lines 18-20). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an external tube made of PTFE in the device of Holsinger et al. because de Toledo et al. teach using PTFE tubing for catheters because it can be easily advanced around bends and is impervious to and compatible with therapeutic and bodily fluids.

19. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holsinger et al. (US 5,843,091) and Andrews et al. (US 6,482,178 B1) as applied to claim 9 above, and further in view of Mickley (US 2003/0216693).

With regard to claims 17 and 18, Holsinger et al. teach a catheter substantially as claimed. Holsinger et al. does not disclose the needle to be made of steel or a rigidity enabling sharp bends. However, Mickley shows a stainless steel component which is capable of making sharp bends (Fig. 1 shaft 136, [0034]). It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to make the needle out of stainless steel because Applicant has not disclosed that such a material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with a needle of a variety of materials as illustrated by Mickley that steel is one of several suitable options and further, it is routine to use steel components in the body because of their

biocompatibility. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the needle out of steel in the device of Holsinger et al. because steel is a known material used for its biocompatibility and further Mickley shows that steel materials are capable of making bends.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767